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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,560	02/22/2000	Kenneth Iain Cumming	00.1090.US	3011

7590

06/04/2004

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/510,560

Applicant(s)

CUMMING ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-39,41,42 and 49-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-39,41,42 and 49-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/28/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement: Applicant's Amendment filed April 13, 2003 is acknowledged.

Status of Claims

1. The status of the claims is as follows:
 - a. Claims 2, 40, 43-46 and 48 are cancelled in view of applicant's amendment.
 - b. Claims 1, 3-39, 41, 42, 47 and 49-66 are pending.

Claim Rejections-35 USC Sec 102

2. Claims 1, 3-13, 15-39, 41, 42 and 49-52 remain rejected under 35 USC 102(b) as being anticipated by Watts et al (WO 97/05903) as set forth in the previous office action.

Claim Rejections-35 USC Sec 103

3. Claims 1, 3-39, 41, 42, 47 and 49-52 and 53-66 remain rejected under 35 USC 103(a) as being unpatentable over Watts et al (WO 97/05903) as set forth and discussed in the previous office action.

Response To Arguments

4. Applicants arguments filed February 25, 2004 have been fully considered but they are found not persuasive.
5. Applicant argues that the Watts reference teaches that the constituents that make up the dosage form include liquid constituents but that the composition that makes up the dosage form is a semi-solid or liquid composition. Applicant further argues that applicant's composition is distinguished from that taught by the prior art as applicant's constituents defining applicant's composition are all solids at room temperature and the composition making up the dosage form is solid.

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6. In response to this argument, the examiner takes the position that a composition is a generic term. Generic claims permit broad interpretation and on that basis, one of ordinary skill in the art would know and hence would be able to select a solid or liquid as the starting constituent for making the composition. Succinctly, the broad interpretation permitted under the generic term "composition" makes it irrelevant whether the starting constituents used for making the composition are solid, semi-solid or solid (see Patent WO '903 at page 8, lin 20).

7. Applicant argues that the Watt's reference, as distinguished from applicant's invention, teaches a liquid or semi-solid composition comprising a drug and enhancer. Applicant further argues that because liquid or semi-solid form of the composition is advantageous for enhancing drug absorption through a target membrane such as found in the colon; and as the Watt's reference teaches that a fatty acid-based constituent alone is ineffective for enhancing drug absorption, that the prior art cited by examiner teaches away from applicant's solid drug and enhancer composition which comprises a mixture in which each constituent is a solid at room temperature.

8. In response, applicant assumes the burden of establishing the criticality for the use of only one form of enhancer wherein the only enhancer present in the dosage form is selected from a group consisting of salt of fatty acid that can be used for preparing the dosage formulation. In other words, applicant assumes the burden of establishing that the presence of liquid form of enhancer is detrimental to the preparation of the composition and/or that the use of a salt as enhancer contributes to success.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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